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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,763	06/29/2000	Hui Chen	1440.1043-001	7609

21005 7590 10/21/2003

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

20

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/606,763

Applicant(s)

CHEN ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12,13,17,19,38-42 and 91 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☒ Claim(s) 38,40,41 and 91 is/are ~~allowed~~ *free of art*.

- 6) ☒ Claim(s) 12,13,17,19,39 and 42 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 19
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The finality of the previous Office Action mailed June 10, 2003 (Paper No. 17) is withdrawn because of a new ground of rejection.

Status of the Claims

2. Claims 12, 13, 17, 19, 38-42 and 91 are pending.

Applicants' amendment filed on August 8, 2003 (Paper No. 18) is acknowledged, and applicants' response has been fully considered. ~~Claims 37 and 90 have been cancelled. Thus, claims 12, 13, 17, 19, 38-42 and 91 are examined.~~

Rejection Withdrawn

Claim Rejections - 35 USC § 102

3. The previous rejection of claims 37 and 90 under 35 U.S.C. 102(a) as being anticipated by Heinigard *et al.* (WO 98/46253), is withdrawn in view of applicants' cancellation of the claims in Paper No. 18.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 12, 13, 17, 19, 39 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 12 and 13 are indefinite as to how different bands (e.g., "50 kDa and 55 kDa" or "62 kDa or 67 kDa") are produced when the claims merely indicate human cartilage oligomeric matrix protein is cleaved by trypsin.

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6. Claims 17 and 19 are indefinite because of the use of the term "ELISA". The term "ELISA" renders the claim indefinite, it is not clear what the term means. A fully spelled out word should be indicated. Claims 17 and 19 are also indefinite as to what else are included in the kit besides human cartilage oligomeric matrix protein since the term "comprising" is cited in the claim.

7. Claim 39 is indefinite because of the use of the term "a differentiation agent".

The term "a differentiation agent" renders the claim indefinite, it is unclear what

~~compound is used as a differentiation agent, and what the differentiation agent will do~~

because no cells are included in the composition.

8. Claim 42 is indefinite as to whether collagens include type I collagen gel or type II collagen gel since the claim recites the matrix comprises type I collagen gel or type II collagen gel and further comprises collagens.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Newton *et al.* (Genomics 24, 435-439 (1994)).

Newton *et al.* teach human cartilage oligomeric matrix protein (hCOMP) has been cloned and sequenced (Accession No. L32137; page 435 right column-page 436, left

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column, first paragraph, and right column). Since the peptide sequence of hCOMP has been determined, the hCOMP is purified and it would be expected to obtain the digested bands of "50 kDa and 55 kDa" or "62 kDa or 67 kDa" when hCOMP is cleaved by trypsin (claims 12 and 13).

10. Claim 42 is rejected under 35 U.S.C. 102(a) as being anticipated by Heinegard *et al.* (WO 98/46253).

Heinegard *et al.* teach a pharmaceutical composition comprising COMP, fragments or analogs for prevention or treatment of arthritic conditions. The pharmaceutical composition comprises a purified bovine, rat or human COMP (page 6, lines 3-20; page 9, lines 14-27; page 15, lines 7-14, 23-28) and one or more arthritogenic substances such as collagen II, IX or XI, or aggrecan (page 15, lines 1-6; claim 42).

Conclusion

11. Claims 12, 13, 17, 19, 39 and 42 are rejected. It appears claims 38, 40, 41 and 91 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

October 16, 2003

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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